DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

TB Notes
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Dear Colleague:

It is time again for state and big city tuberculosis (TB) and laboratory program staff to start working on TB cooperative agreement proposals for fiscal year 1996. Consistent with CDC's intent to streamline the process, we have significantly reduced the amount of information that is required and thus the amount of administrative time that must be spent preparing the request for funds. The new application requirements were spelled out in a June letter sent to TB program and laboratory directors.

We can be pleased that, for the second consecutive year, overall TB cases reported in the United States have declined. We believe recent increases in TB funding have enabled us to undertake actions that are largely responsible for these decreases. Health departments in States and cities across the nation have been able to target funds to address TB in high-risk populations. For example, New York City (which has the single largest number of TB cases) has reported their second year of decreasing TB cases. This city was able to mobilize the new resources to expand public health services, institute directly observed therapy (DOT), initiate multidrug-resistant (MDR) TB outbreak control efforts, and establish new prevention and control activities for high-risk populations.

Based on the best information available at the time of this writing, it is likely that we will continue to have categorical funding available for the 1996 TB cooperative agreement process, and it appears that funding will be at approximately the same level as in 1995. As we know from history, TB control is an exercise in vigilance. If not managed correctly, TB cases will increase, often presenting more difficult and expensive problems such as those posed by MDR TB cases. To ensure continued availability of necessary resources, we must demonstrate effective and efficient use of resources, both human and fiscal. Data available through existing program management reports, from SURVS-TB, and potentially from TIMS, can be used to assess program performance according to traditional evaluation indicators for continuity and completion of therapy. The top priority for our Program Services Branch will be to continue working with health departments in the coming year to assist in efforts to improve completion of therapy rates for TB patients. Medical officers will work closely with consultants through telephone and on-site consultations to help evaluate trends in therapy completion, determine the effectiveness of State and local programs regarding completion of therapy, and assist in developing and carrying out effective interventions needed to address identified problems (e.g., expanded use of DOT and incentives, use of cohort reviews, and more effective coordination with other health care providers).

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The Advisory Council for the Elimination of Tuberculosis (ACET) met on April 26-27 in Atlanta. After discussing tuberculosis in foreign-born persons, including immigrants and refugees, ACET decided to formally address the various issues and make recommendations to the Secretary of the Department of Health and Human Services. There was a discussion about the NIOSH and OSHA rule changes concerning respiratory protection for TB infection control. The NIOSH rule change, which was published in the *Federal Register* June 8, allows users to choose from a broader selection of NIOSH-certified respirators. OSHA is developing a new TB standard to address infection control and respiratory protection in health care settings; in the meantime, OSHA has indicated that it will incorporate the new NIOSH standards governing filter penetration. Please see the related article in this issue. The council then continued its review of the nation's progress toward TB elimination. The council also discussed TB/AIDS surveillance coordination efforts, the reorganization of the new center, and funding issues.

There is renewed interest in drug susceptibility testing since CDC has determined that the majority of BACTEC users are not using the recommended concentrations for two of the primary drugs, streptomycin and ethambutol. Dr. John Ridderhof of the Public Health Practice Program Office, CDC, has contributed an article on this subject.

All five of the restriction fragment length polymorphism (RFLP) regional laboratories, as well as the CDC laboratory, are up and running and are receiving samples from various State health departments and hospitals. Each laboratory is processing an average of 150-200 isolates per month, and the number of strains is growing rapidly. We have designated Dr. Christopher Braden, medical epidemiologist in the Surveillance and Epidemiologic Investigations Branch, to work closely with our colleagues at CDC in the National Center for Infectious Diseases in a concerted effort to appropriately link epidemiology and laboratory science. Dr. Peter Small's group in San Francisco is working on the problem of how to exchange data on strains between laboratories.

As described in a previous issue of *TB Notes*, the Robert Wood Johnson Foundation provided funding in 1994 to five TB prevention and treatment projects targeting high-risk, hard-to-reach populations (*TB Notes* Summer 1994). The Foundation, receiving many more proposals than it was able to fund, consolidated some of the proposed projects into an article for distribution to anyone interested in the use of incentives. The article describing these creative suggestions is an attachment to this issue.

Kenneth G. Castro, M.D.

In This Issue

NOTE: The use of trade names in this issue is for identification only and does not imply endorsement by the Public Health Service or the U.S. Department of Health and Human Services.

HIGHLIGHTS FROM STATE AND LOCAL PROGRAMS

Update on the DOT Experience in New York City

Over the past several years, the New York City Department of Health (NYCDOH) has increased the number of patients on directly observed therapy (DOT) dramatically, from less than 100 to more than 1300. Expansion of DOT has resulted in improved rates of treatment completion and reduced tuberculosis morbidity. In the course of this expansion, the staff of the NYCDOH have learned many lessons. A discussion of some of these illustrative issues encountered by the NYCDOH may be of interest to other programs.

The challenges encountered by the NYCDOH have fallen into two categories: 1) attitudes and priorities of health care staff and patients, and 2) logistics. This article discusses the significance of these challenges and what factors might be considered in resolving them.

Changing Attitudes and Priorities
The NYCDOH found it essential to elevate the status of DOT workers — they are the true public health heroes of modern times. The culture of TB programs should emphasize respect for these workers' role. Prior to the DOT expansion, DOT was often not considered an important assignment.

For a DOT program to be established or expanded, the habits and resistance of patients,
physicians, and public health staff must be overcome. Conceptualizing DOT as the standard of care helps, as does requiring physicians to document why any patient is not on DOT, and explaining to patients that “DOT is simply the way we do it." Another way to help convince staff and patients is to share with them published literature documenting that DOT improves patients' chances for cure and contributes to effective TB control.[1,2] In extreme cases, court- or Commissioner-ordered DOT is used; patients who fail this intervention may warrant detention until cured.

Patients often attempt to bargain down the number of pills taken by DOT, promising to take the rest later. Outreach workers can learn to improve patient compliance with all medications through role playing, ongoing training,

and skills-building. Often outreach workers and physicians can work together to simplify medicine regimens.

Daily therapy can be particularly undermining of a DOT program. Many patients are inconvenienced by having to meet on a daily basis for DOT. Also, patients who are given DOT during the week and take-home doses for the weekend understandably wonder why they cannot also take their weekday doses on their own. Intermittent therapy for patients with drug-susceptible isolates is effective and less expensive than daily treatment and ensures that every dose is observed.

Many physicians and patients are unfamiliar and uncomfortable with intermittent therapy. Patients may be concerned about the efficacy of intermittent medication or about the lethargy sometimes associated with high-dose intermittent isoniazid, or may have a perceived need for daily contact with the program. And many physicians need education, role models, and persuasion to change longstanding habits, even though intermittent therapy is clearly documented to be at least as effective as daily therapy for drug-susceptible tuberculosis (and more effective in an animal model). Making intermittent therapy the standard of care is essential to changing physicians' practices and patients' cooperation regarding intermittent DOT.

An overemphasis on increasing the number of patients on DOT may cause TB programs to lose sight of their public health priorities. Although it would be ideal to give DOT to every patient, it is most important from a public health standpoint to ensure DOT for patients with positive smears, cavitation on chest radiographs, or drug-resistant isolates. The paramount aim of a tuberculosis control program is to ensure treatment completion; DOT is one way to do this.

Changing Logistics or Procedures

Providing training to staff members at all levels—from physicians and nurses to clerical staff—is key. Private space to provide DOT is also very important. The increased number of patient visits to on-site DOT programs can increase crowding in already overstressed public clinics. Giving DOT for a year to 100 patients translates to roughly 16,000 additional visits.

Managing and making sense of DOT data is a challenge. In one year, a single clinic with 100 patients on DOT generates more than 100,000 bits of information about DOT alone: whether medications are taken every day, which medications are taken, what was done to locate patients who missed their doses, documentation of incentives disbursed, etc. Using a computerized database, the NYCDOH generates monthly reports by provider and patient. It is critical to provide ongoing training and supervision in the recording, collection, and submission of data, and in interpreting this data for day-to-day program management.

The optimal mix of in-clinic vs. in-field

DOT can be difficult to determine. In-clinic DOT has the advantages of efficiency, staff safety, and medical backup. In-field DOT is usually more convenient for patients but requires more staffing and staff oversight. In New York City, providing DOT in the clinic was new, while there was a 10-year tradition of providing DOT in the field. DOT can be provided in drug treatment programs, single room occupancy hotels, prisons and jails, and shelters, as well as more nontraditional sites such as bars, parks, and abandoned buildings.

Because patients on DOT frequently have questions or symptoms which require nursing or medical assessment, the NYCDOH finds it important to have physicians available when DOT patients are present. Also, although ongoing DOT is provided by outreach workers, the first 2 weeks of clinic-based DOT is given by a registered nurse. Ongoing, respectful communication between patients, outreach workers, and medical professionals is essential.

Legal issues of administering medications must also be resolved. In New York State, any individual can observe as patients take their medications, but only a doctor or nurse or related health professional can actually administer medications to a patient.

In addition to New York City's program, the New York State DOH and Department of Social Services established a supplementary team of DOT providers who are outside the DOH. This program leverages additional resources for DOT via Medicaid and other funds, and increases the number of settings in which DOT can be offered. As long as non-DOH programs operate effectively, communicate well with the DOH, and refer nonadherent patients for follow-up promptly, these providers can be an important asset.

Patients on injectable therapy are often seen by a visiting nurse service. Many such services have the health model of teaching patients to self-administer injections and other medications. NYCDOH staff now either provide injectable therapy themselves, work with the visiting nurse service to ensure that they continue to observe injections, or have outreach workers observe both oral and patient-administered injectable medications. Visiting nurses must either learn to observe oral medications or work in conjunction with outreach workers who will do this.

Split doses can be given in a DOT program. Second-line medications are generally given in multiple doses per day, but observing more than one dose per day is sometimes only feasible in an outpatient setting. NYCDOH staff sometimes compromise by giving adults medications such as cycloserine and ethionamide 500 mg in an observed morning dose, with 250 mg to be taken unobserved later. With both of these medications, thrice daily dosing might be more effective and less toxic, but the twice-daily regimen ensures that what is

likely to be a minimally effective dose is observed. This dosage schedule represents a reasonable compromise to achieve a workable program.

An important part of a successful DOT program is providing incentives and enablers to patients to encourage therapy adherence. It is critical to clearly explain the necessity of incentives to local decision-makers and to have detailed systems to prevent theft and to ensure accountability. Providing food to patients receiving DOT raises issues of the cleanliness or quality of the food and monotony of the menus. Some patients may be too proud to ask for or accept an offer of food, while others are insulted by the offer. On the other hand, for some patients, the food provided is their only meal. The best incentive is a good relationship between patient and DOT worker.

Everything from flat tires to traffic jams to unexpected delays makes the provision of in-field DOT logistically challenging. For example, DOT requires transportation; access to cars raises issues of parking, liability, insurance, maintenance, gasoline purchase, accidents, screening for illicit substances after accidents, etc. Also, many apartment buildings in New York City lack functional buzzer systems; outreach workers are often given building keys, but this may raise issues of worker safety and liability. Creative solutions and flexibility are key.

A safe work environment is critical for outreach workers; they must feel secure when interacting with patients. For example, patients on DOT may be infectious; it is essential to provide good ventilation, ultraviolet lights, and effective personal respiratory protection in appropriate situations. (Interestingly, since the inception of DOT, NYCDOH staff have noted a substantial decrease in the number of infectious patients being seen in their clinics, presumably because of better patient adherence.) Workers may also be placed at risk by increased contact with persons (or their neighbors) who may be under the influence of alcohol, cocaine, or heroin, or who have mental illness or a record of criminal activity. The presence of incentives with financial value (such as tokens or fast-food coupons) makes security an even greater concern. In potentially unsafe situations, workers are authorized to travel in pairs.

Many TB patients are HIV infected; outreach workers must learn to cope with death and dying. Workers may be the first to have contact with a critically ill or moribund patient. All persons involved in the care of patients must understand that even when a patient dies, the treatment of his or her tuberculosis has had the positive result, beyond the public health benefits, of making the patient's life happier, healthier, longer, and less isolated.

Many patients are completely compliant with DOT, but repeatedly fail to attend physician visits. Ongoing persuasion and arrangement of child care and transportation often help. One poignant

situation which arises surprisingly often is the patient's refusal to attend the last scheduled medical visit. Many patients become so attached to their outreach worker and the DOT program that, either consciously or subconsciously, they are unwilling to part company. By missing their last medical visit, they may prolong treatment unnecessarily for as long as their medication supply lasts. This situation, which DOT workers can often resolve by gently but directly confronting the issue, is a striking testament to the deep human bonds which develop during DOT. A program of hiring cured patients as assistant outreach workers allows selected patients to continue to have this contact, while enriching the outreach program and providing ideal role models for future patients.

—Reported by Tom Frieden, Marie Dorsinville, Fran DeLott, Paula Fujiwara, Laurie Gulaid, Toni Davis, and Chris Larkin
New York City TB Program

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2. Weis SE, Slocum PC, Blais FX, et al. The effect of directly observed therapy on the rates of drug resistance and relapse in tuberculosis. *N Engl J Med*. 1994;330(17):1179-1184.

Educational Materials in Asian/Pacific Islander Languages

In the United States, Asian and Pacific Islander immigrants and refugees are at high risk for TB because many members of these populations have recently arrived from countries where TB is common. Between 1980 and 1990, the foreign-born population in this country increased by over 40%; during this period the top five countries contributing immigrants to this country were Mexico, the Philippines, Vietnam, China, and Korea. [1] The TB incidence rates in these countries are 10 to 30 times greater than the rate in the United States. These groups vary greatly in terms of language, cultural traditions, and health beliefs and practices. Since TB control resources are at times not adequate to address the social, cultural, and economic aspects of TB control, Asians and Pacific Islanders may not receive needed education and health services.

In 1993, CDC announced a 5-year project to provide funding to national

and regional minority organizations (NMOs/RMOs) to augment national prevention efforts for STDs/HIV, immunization, and TB by broadening current partnerships and strengthening NMO/RMO disease prevention capacities. The Association of Asian Pacific Community Health Organizations (AAPCHO) was awarded the TB project, and in October 1993 CDC began funding AAPCHO to address some of the social, cultural, and medical aspects of TB prevention and control in Asian and Pacific Islander populations.

The AAPCHO-funded TB project, the National Asian Pacific Islanders TB Initiative (the TB Initiative), works with agencies serving high-risk (e.g., newly arrived) Asians and Pacific Islanders. AAPCHO will use many strategies to promote culturally and linguistically appropriate services, including education and training for service providers; resource sharing among local and regional health care facilities; dissemination of health information through public health campaigns; and collaboration with hospitals, community health centers, community based organizations, and state and local health departments.

Activities of the first phase, now completed, included conducting regional workshops and focus groups as well as evaluating and translating TB patient education materials into several Asian/Pacific Islander languages. As a result of these activities, a list of recommended TB materials was developed and has been made available. (A copy of the list can be found at the end of *TB Notes* as an attachment.) AAPCHO collected TB-related educational materials used across the nation at ALA chapters, AAPCHO community health centers, community based organizations, state and local health departments, and other agencies. Preference was given to materials available in English and at least one Asian or Pacific Islander language. The materials were reviewed by members of a multilingual review panel for linguistic accuracy and cultural appropriateness. Materials receiving approval from that panel were then given to a program review panel for review for clinical accuracy in accordance with CDC guidelines. The list indicates specific titles, language availability, and source. The languages in which the materials are available include Tagalog and Ilocano (Philippine languages), Vietnamese, Chinese, and Korean. These materials are intended to provide basic information about TB, at a low literacy level, to the Asian/Pacific Islander general public. This list should not be considered exhaustive; AAPCHO welcomes suggestions for needed TB materials as well as copies of additional TB-related materials not included in the list that might be reviewed for inclusion. AAPCHO will provide at no charge *one* copy of any title on the list; to order, contact Mr. Jeff Caballero at (510) 272-9536. For information on ordering multiple copies, contact the vendor directly; in some cases, there may be a charge for the materials.

Future activities of the TB Initiative will include:

- Developing new materials based on the needs identified
- Developing cross-cultural communication materials for health care workers who provide TB services for persons from the Philippines, Vietnam, China, and Korea
- Creating and strengthening partnerships between local health departments, AAPCHO-affiliated community health centers, and other CBOs to provide TB services
- Analyzing and reporting Asian/Pacific Islander focus group data that describe and compare TB beliefs and treatment concerns

—Reported by Jeff Caballero AAPCHO

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1. McKenna MT, McCray E, Onorato I. The epidemiology of tuberculosis among foreign-born persons in the United States, 1986-1993. *N Engl J Med*. 1995;332:1071-76.

Drug Resistance in Washington State, 1994

A 1984 Washington State study declared that all cultures of *M. tuberculosis* should be tested for drug sensitivity; this practice is encouraged in the state of Washington. [1] All local health jurisdictions and the majority of hospitals and laboratories send specimens for bacteriology (sputum smear and culture and drug resistance/drug susceptibility testing) to the Washington State Department of Health Public Health Laboratory in Seattle. The state lab performs susceptibility testing on all initial positive cultures. Repeat susceptibility tests are requested by the state TB program under the following circumstances:

- The patient has positive cultures for over 3 months
- A positive culture follows the conversion
- Irregular therapy (e.g., nonadherence) is suspected

For 1994 there were a total of 264 cases of *M. tuberculosis,* down from 286 for 1993 (a 7.6% decrease). In February 1995 there were 248 cases available for analysis; 113 cases (45.6%) were in U.S.-born persons and 135 (54.4%) were in foreign-born persons. There were 215 susceptibility test results available; 98 of these 215 results are for persons born in the U.S. and 117 are for foreign-born persons.

Resistance to one or more drugs was found in eight U.S.-born patients (8.3%). The results, by individual drug, were as follows:

INH	RIF	PZA	SM	EMB	I & R
6 6.1 %	1 1%	0	3 3%	1 1%	0

Resistance to INH and RIF was found in two foreign-born persons :

Country	No. Tested	No.(%) MDR
Philippines	17	1 (5.9)
Vietnam	20	1 (5.0)

Data on U.S.-born persons with resistance to at least one drug, by age group, are as follows:

Age	No. Cases	No. Tested	No. Resist.	% Resist.
0-14	12	4	0	0
15-24	2	2	0	0
25-44	36	34	4	11.8
45-64	34	31	2	6.5
65+	29	25	2	8.0
Total	113	96	8	8.3

Data on foreign-born persons with resistance to at least one drug, by age group, are as follows:

Age	No. Cases	No. Tested	No. Resist.	% Resist.
0-14	8	3	2	66.6
15-24	27	23	3	13.0
25-44	46	42	10	23.8
45-64	33	28	3	10.7
65+	21	21	3	14.3
Total	135	117	21	17.9

The following are susceptibility results for foreign-born persons by country of origin:

Country	No. Tested	INH No.(%)	RIF No.(%)	PZA No.(%)	SM No.(%)	EMB No.(%)	ETA No.(%)
Philipp's.	17	8 (47.1)	1 (5.9)	0	1 (5.9)	0	0
Vietnam	20	2 (10)	1 (5)	0	0	0	0
Mexico	24	3 (12.5)	0	0	1 (4.2)	0	0
Somalia	3	1 (33.3)	0	0	1 (33.3)	0	0
Russia	5	1 (20)	0	1 (20)	0	0	0
China	5	0	0	0	1 (20)	0	0
All Others	43	0	0	0	1 (2.3)	0	0
Totals	117	15 (12.8)	2 (1.7)	1 (0.9)	5 (4.3)	0	0

Resistance to TB drugs was significantly higher in foreign-born than in U.S.-born persons. Of the 117 foreign-born TB patients for whom drug susceptibility results were available, 21 had isolates resistant to at least one drug (17.9%).

The results thus far show INH resistance of 6.1% in U.S.-born persons, compared to 12.8% in foreign-born persons (representing 6 of 26 countries). These data warrant the use of four drugs in the initial regimen until drug susceptibility results are obtained.

Analysis and review of drug resistance data for Washington State confirms that 2 cases (1.1%) are multidrug resistant. Resistance to streptomycin is 7.6%, precluding this choice as the fourth drug. This information will help local health districts and medical practitioners determine optimal treatment regimens and patient management strategies to ensure completion of therapy. [2]

—Reported by Kim Field
Washington TB Program

References

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2. Bloch AB, Cauthen GM, Onorato IM et al. Nationwide survey of drug-resistant tuberculosis in the United States. *JAMA*. 1994;271:665-671.

Portland: Inner City TB Rates Decline with Long-Term Interventions

In recent years, Oregon has had a tuberculosis (TB) case rate of about 5 per 100,000. However, the Burnside inner-city area of Portland, which has many transient and homeless residents, has been an exception with case rates many times higher than the rest of the state. The Multnomah County TB Clinic (MCTC) began to focus TB intervention efforts in the area in the 1980s.

Multnomah County's program offers TB education, screening, skin testing, and directly observed therapy (DOT). Many of these services are offered at biweekly screenings in the focus area. Screening is offered in the lobby of a local single room occupancy (SRO) hotel by public health nurses and outreach workers. Individuals with positive skin tests or signs and symptoms of TB are escorted to MCTC, a short walk from the hotel. TB clearance cards are issued to those who complete screening. The fact that many of the shelters in the area require TB clearance before admission has been an incentive for residents of the area to use TB services. Beginning in 1985, DOT has been implemented for all cases in the Burnside area.

The incidence of TB in the Burnside area declined from 238 per 100,000 in 1980 to 39 per 100,000 in 1994. The incidence of recurrent TB cases declined from 27 per 100,000 in 1986 to none in 1994. The data strongly suggest that the decline in TB in this area is due to MCTC's continued efforts, which have been supported in part by CDC cooperative agreement funds. Factors contributing to the success of this program include the long-term commitment of funding and staff for TB control.

—Reported by Liz Binam and Beth Brown
Oregon TB Program

UPDATE FROM THE LABORATORY

Assessing the Performance of Drug Susceptibility Testing for *Mycobacterium tuberculosis* in U.S. Laboratories

The National Action Plan to Combat Multidrug-Resistant Tuberculosis, MMWR 1992;41(No. RR-11), contained several recommendations for increased laboratory support and assessment. These recommendations prompted CDC to implement a performance evaluation program for *M. tuberculosis* drug susceptibility testing. This is a voluntary program that uses actual patient cultures of *M. tuberculosis* to provide, free of charge, anonymous evaluations of laboratory testing methods. A contractor (DynCorp, Research Triangle Park, N.C.) provides laboratory enrollment, shipment of *M. tuberculosis* strains, data collection, and data entry. CDC compiles the data from each shipment of *M. tuberculosis* strains and provides this data to all participating laboratories, with some analysis of common problems and testing characteristics. This program

report provides the staff of each participating laboratory with a self-assessment of test performance and an opportunity to compare their laboratory practices with other laboratories performing *M. tuberculosis* drug susceptibility testing. Using information provided by proficiency testing programs, CDC estimates that 50% of U.S. laboratories performing *M. tuberculosis* drug susceptibility testing are enrolled in the program.

The 137 laboratories that participated in the August 1994 shipment of strains represented a cross-section of laboratory types (62 hospitals, 63 health departments, 10 independent laboratories, and 2 others). The methods used to perform susceptibility testing were as follows: 68 laboratories used the BACTEC® method, 30 used the conventional method, and 34 used these methods in combination. The laboratories that participate in the CDC *M. tuberculosis* performance evaluation program are not necessarily a representative sample of U.S. laboratories; there is a high proportion of BACTEC® users compared to proficiency testing program enrollees as well as a high percentage of health department laboratories; there is also self-selection bias by participation. These participating laboratories, however, provide some insight into laboratory concerns, such as the proportion of laboratories located in a biosafety level 2 facility (28%) rather than the recommended level 3 facility. Although the majority of participants use the recommended radiometric methods, use of the slower conventional methods is not associated with annual volume and occurs in laboratories processing ≥320 *M. tuberculosis* isolates per year.

Through analysis of the primary drug concentrations used by laboratories, CDC found a problem that all TB control programs should be aware of. Although most participants offer testing for streptomycin, isoniazid, rifampin, and ethambutol (only 53% test pyrazinamide), **the majority of BACTEC® users (>60%) were not testing with the recommended critical concentrations for streptomycin (2.0 µg/ml) and ethambutol (2.5 µg/ml). The manufacturer of BACTEC®, Becton-Dickinson, has revised the manual to highlight and alert laboratories to the recommended concentrations.** The critical concentration of an antituberculous drug is the concentration that inhibits the majority of wild strains of *M. tuberculosis* but does not affect the growth of resistant mutants. These labs were testing with higher concentrations of streptomycin and ethambutol, which may lead to an inability to detect emerging resistance to these drugs. While there needs to be further research on the role of minimal inhibitory concentrations in clinical management of the patient, laboratories should be using BACTEC® concentrations equivalent to the original critical concentrations that were determined in solid media (Lowenstein-Jensen and Middlebrook 7H10).

In addition to analyzing the drug concentrations, CDC also examined the testing performance of participant laboratories and found that the quality of testing with the combined BACTEC® and conventional methods was good. For the recommended concentrations of the primary antituberculous drugs, the analysis showed discordant results of only 2% for each method (46/2332-BACTEC®; 32/1617-conventional). Although there was no discordance associated with laboratory type, annual volume, or method used, this performance evaluation program cannot measure common problems such as cross-contamination and mixed cultures.

In summary, analyses of both performance and practices for *M. tuberculosis* drug susceptibility testing provide an important self-assessment for supporting the laboratory's crucial role in controlling MDR TB.

—Reported by John Ridderhof, Robert Good, Harold Muir, Roger Taylor, Ronald Fehd, James Handsfield, John Langtim
Public Health Practice Program Office

OSHA Respiratory Protection Standards and NIOSH Certification

The OSHA respiratory protection standard requires certification by the National Institute for Occupational Safety and Health (NIOSH) of all respiratory protective devices used in the workplace. NIOSH-approved high efficiency particulate air (HEPA) respirators have been the only available air-purifying respirators that met or exceeded the standard performance criteria recommended by the CDC. On July 10, 1995, however, NIOSH updated its respirator testing and certification requirement to enable workers, including hospital employees caring for patients with highly infectious tuberculosis, to identify cost-efficient respirators that will effectively meet their health and safety needs. This new requirement was developed with input from safety professionals, respirator manufacturers, representatives of health care facilities, and affected workers.

Under the new particulate filter tests, NIOSH will certify three classes of filters (N-, R-, and P-series), with three levels of filter efficiency (95%, 99%, and 99.97%) in each class. All filter tests will employ the most penetrating aerosol size: an aerodynamic mass with a median diameter of 0.3 µm. The R- and P-series of filters will be tested using a highly degrading aerosol of dioctylphthalate (DOP) and so are more applicable to industrial needs. The N-series filters will be tested using a mildly degrading aerosol of sodium chloride (NaCl). Tested to a specified maximum loading level (200 mg), the N-series filters will be restricted to workplaces that are free of oil or other severely degrading aerosols.

All nine categories of air-purifying particulate respirators exceed the filter performance criterion recommended by the CDC to prevent the transmission of *M. tuberculosis* in health care facilities.

Respirators that contain a NIOSH-certified **N-series filter with a 95% efficiency (N-95) rating** will be appropriate for use in accordance with the CDC guidelines. The certification of air-purifying respirators under the final rule will enable respirator users to select from a broader range of certified respirators, several of which are expected to be less expensive than respirators with HEPA filters. A few of the currently available dust-fume-mist respirators may be re-certified at the N-95 level under the new NIOSH requirement.

OSHA is developing a new TB standard to address infection control and respiratory protection in health care settings; in the meantime, OSHA has indicated that it will incorporate the new NIOSH standards governing filter penetration. Further information on respirator certification may be found in the NIOSH standards, which were published on June 8 in the *Federal Register*. A technical summary and the full text of the regulation can be obtained by calling the NIOSH toll-free information number at 1 (800) 35-NIOSH (select option 5) or downloaded from the NIOSH World Wide Web page (http://www.cdc.gov/niosh/homepage.html). A summary of the CDC's current guidelines on respiratory protection can be ordered through the Tuberculosis Fax System by calling (404) 332-4565 and requesting document #250135. The complete CDC *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities, 1994*, published in October 1994, can be ordered by calling (404) 639-1819.

NIOSH is a part of the CDC within the U.S. Public Health Service, Department of Health and Human Services. The CDC is not a regulatory agency, and its recommendations on infection control are not regulations. For regulations in your area, contact your state or local OSHA office.

—Reported by Susan M. Graham, M.P.H.
Pattie M. Simone, M.D.
Division of TB Elimination

Discussion of Issues Regarding Rifater®

Rifater®, a fixed-dose combination tablet of 50mg of isoniazid, 120 mg of rifampin, and 300mg of pyrazinamide, manufactured by Marion Merrell Dow Inc., has been available in the United States for the treatment of TB for a little more than a year. The most recent American Thoracic Society (ATS)/CDC statement on the treatment of TB strongly encourages the use of fixed-drug combinations for the treatment of TB in adults on self-administered therapy because they may simplify the regimen and improve patient adherence, reduce the risk of inappropriate monotherapy, and help prevent the emergence of drug resistance.[1] However, a number of TB controllers and physicians have asked questions and expressed concern about the use of this product because the recommended dosing of six Rifater®

tablets for patients weighing 55kg or more provides a 720mg dose of rifampin, which exceeds the 600mg maximum dose of rifampin recommended in ATS/CDC statements.

The difference in rifampin dose is due to the reduced bioavailability of this drug in the combination tablet. Data presented in the Rifater® package insert indicate that, while the bioavailability of isoniazid and of pyrazinamide are similar whether the three drugs are given simultaneously as separate drugs or in the fixed-dose combination tablet, the bioavailability of rifampin from the combination tablet is only 88% of that obtained when the separate drugs are given simultaneously. Additional analysis of these data, presented to the Food and Drug Administration (FDA), shows that the 90% confidence interval around the ratio of the peak serum levels of 600mg rifampin from the two formulations (combination tablet: individual drugs given simultaneously) was .743 to .886, and the 90% confidence interval around the ratio of the areas under the curve was .814 to .932. Other data presented to the FDA show that the greatest level of bioavailability of rifampin is obtained when rifampin is given alone, with an intermediate level obtained when it is administered in the combination tablet. Thus, increasing the dose of rifampin by about 20% from approximately 10 mg/kg (maximum 600 mg) to 12 mg/kg (maximum 720 mg) may overcome the roughly 20% reduction in bioavailability, even though the peak serum level of rifampin obtained following a 600mg dose of rifampin in the combination tablet is still more than 20 times the minimal inhibitory concentration (MIC) of rifampin for most strains of *M. tuberculosis.*

The increased dosage of rifampin in the combination tablet appears to be equally efficacious and equally well tolerated. In one randomized, controlled trial comparing this formulation of Rifater® with the three drugs given separately in the induction phase of short-course chemotherapy [2], 125 patients were randomized to each regimen and followed for 2 years for sputum conversion, occurrence of adverse reactions, and relapse. Data from this trial, presented in the package insert, show that the sputum conversion rates and the time to sputum conversion were nearly identical, and there were no relapses among either group of patients. Comparing adverse reactions, 29 of 122 (23.8%) patients randomized to receive Rifater® and 43 of 123 (35.0%) patients randomized to receive the three drugs separately reported one or more adverse reactions. This difference just fails to reach statistical significance (95% confidence interval, -.1% to 22.5%). A subanalysis of this data compared patients weighing more than 55 kg and randomized to receive 720 mg of rifampin in Rifater® against patients weighing 50 kg or more and randomized to receive 600 mg of rifampin in separate tablets. The analysis showed that 15 of 54 (27.8%) patients randomized to receive Rifater® reported one or more adverse reactions while 31 of 90 (34.4%) patients

randomized to receive separate tablets reported adverse events. The 6.6% difference is not statistically significant (95% confidence interval on the difference, -8.9% to 22.1%) and clearly does not indicate any increased risk of toxicity from the 720 mg dose of rifampin in the combination tablet. Only three patients experienced adverse reactions requiring the drugs to be stopped for more than 7 days, all of them were randomized to receive the drugs separately, and all were later successfully rechallenged with the drugs.

These data support the conclusion that this formulation of the fixed-dose combination of isoniazid, rifampin, and pyrazinamide is both safe and efficacious. With the reduced bioavailability of rifampin from the combination tablet, use of this formulation would appear to be consistent with the ATS/CDC recommendations on drug dosages and the use of fixed-dose combination tablets. These data also emphasize the need to better understand the pharmacodynamics of TB drugs, particularly rifampin, and the need for additional research in this area.

Clinicians and TB controllers using fixed-dose combination tablets should be able to ensure the quality of the supplier and the bioavailability of the product. This is of particular concern in developing countries where combination products are often not adequately tested.

—Reported by Larry Geiter
Division of TB Elimination

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Review of DTBE Training and Education Strategy

On April 17-18, 1995, the Division of Tuberculosis Elimination (DTBE) sponsored an external advisory workgroup review of its training and education strategy. Members of the external workgroup represented a broad range of experts in TB control and in training and education, including Mike Holcombe, President of the National TB Controllers' Association (NTCA); Brenda Ashkar, President of the National TB Nurse Consultant Coalition (NTNCC); Wendy Heirendt, representing TB field staff (assigned to

the Indiana State Department of Health); Elizabeth Stoller, representing the Francis J. Curry model TB center; Dr. Lee Reichman, representing the National Coalition for the Elimination of Tuberculosis, the National Institutes of Health (NIH) Academic Awardees, and the New Jersey Medical School model TB center; and Fred Kroger, representing the Health Communications Office at CDC.

DTBE used the workgroup's recommendations as the basis for strategy development by an internal workgroup representing each branch and activity of DTBE. The internal workgroup met on June 29-30 and developed a series of recommendations for developing, monitoring, and evaluating DTBE's training and education strategy. Among other things, both groups gave a very high priority to the revision of the *TB Today!* course for TB controllers, program managers, nurse consultants, and senior level public health advisors with a basic prerequisite level of TB knowledge. The new course will be developed over the next fiscal year by DTBE training and education staff in conjunction with CDC's Public Health Practice Program Office and other collaborating groups (e.g., NTCA and NTNCC) and will be based on an assessment of the skills needed to effectively manage TB programs in today's changing health care environment.

—Reported by Susan M. Graham, M.P.H.
Division of TB Elimination

INTERNATIONAL NOTES

Diversity Immigrant (DV-1) Program

In 1994 approximately 503,000 immigrants were granted visas to enter the United States. Until recently, only those who have close family members in the United States or a sponsoring employer were allowed to immigrate. The Immigration Act of 1990, however, created a diversity immigrant visa lottery program (DV-1) which will award an additional 55,000 immigrant visas annually. This program is designed to benefit natives of "low admission" countries, which include those countries from which fewer than 50,000 persons had immigrated to the United States over the preceding 5 years.

Based on a complex formula, quotas have been established for participating countries and regions. Each country is limited to no more than 3,850 visas annually. In 1995, the program will admit a maximum of approximately 20,000 Africans; 7,000 Asians; 25,000 Europeans; 2,600 South Americans; and 800 residents of Oceania (the lands of the central and southern Pacific). The allotment for fiscal year 1996 is expected to be similar.

In order to qualify for a DV-1 visa, applicants must provide evidence of a high school diploma or its equivalent, or

they must be able to demonstrate that they have had 2 years of work experience during the past 5 years in an occupation that requires at least 2 years of training or experience.

Those applying for DV-1 visas are subject to the same TB screening and classification that other immigrants receive, which consists of a chest radiograph for all persons over 15 years of age and three sputum smears for those whose radiographs are compatible with active tuberculosis (see *TB Notes* Winter 1995). Efforts are underway to ensure the quality of the examinations performed in these countries, many of which have not had significant numbers of immigrants in the past.

Immigration Law Change Affecting Visa Issuance and Adjustment of Status

In the past, certain persons in the United States (e.g., those employed in the United States without authorization or not in compliance with the terms of their nonimmigrant status, or who otherwise entered without a visa status) who wished to apply for permanent residence and to be granted a green card had to return to their country of citizenship and apply through the local U.S. Embassy or consulate. On October 1, 1994, P.L. 103-317 amended Section 245 of the Immigration and Nationality Act (INA) and created a new Section (i) which allows previously ineligible persons and those currently within the United States to apply for permanent resident status in the United States.

Eligibility requirements under the new amendment remain the same as for persons applying through the overseas mechanism, although they must meet additional conditions. First, they must be physically present in the United States at the time of application. Second, they must have entered the United States legally. Third, they must not have been employed in the United States without authorization or violated the terms of their nonimmigrant status.

Although the cost of applying for permanent residence under this amendment is five times higher than through the overseas mechanism ($650 versus $130 for an adult), many may choose this method for its convenience and its cost relative to purchasing a plane ticket home and paying lodging expenses during the processing of the visa applications. A companion provision of the new law which amends INA 212 to add a new Section, 212 (o), further reinforces the relative advantage of adjustment to aliens here who have maintained lawful nonimmigrant status by rendering persons ineligible to apply for immigrant visas until they depart and remain outside the United States for at least 90 days.

Section 245 (i) is a temporary provision that will be effective only until October 1, 1997. While no data are currently available on how many people will ultimately opt to go through Section 245 (i) adjustment instead of consular

processing, that number may be substantial. The State Department estimates that as many as one third of aliens who undergo consular processing overseas each year might be eligible for Section 245 (i) adjustment. In 1994, before the amendments were enacted, there were approximately 314,000 individuals who adjusted their status to that of permanent resident. The Immigration and Naturalization Service (INS) reports that from the beginning of fiscal year 1995 through February 24, 1995, approximately 176,000 applications have been filed and that about 80,000 or 45% of those applications were filed under the new Section 245(i).

Aliens applying for adjustment of status to permanent resident must have a physical and mental examination as part of the application process. The medical examinations are conducted by local physicians (civil surgeons) appointed by the INS following CDC technical instructions (issued by the Division of Quarantine). The tuberculosis screening under this amendment consists of a medical history and physical exam and a tuberculin skin test in all persons over age 2 to determine if the applicant is infected with *Mycobacterium tuberculosis*; a tuberculin skin test is required for those under 2 years of age if there is evidence of contact with a person known to have tuberculosis or if there is other reason to suspect tuberculosis. Persons with reaction sizes of 5mm or greater are required to undergo a chest radiograph, and if the chest radiograph is suggestive of tuberculosis, the civil surgeon must refer the applicant to the local health department for evaluation. Those applicants referred to the health department for further evaluation must return to the civil surgeon with a copy of the evaluation from the local health department before the examination can be completed.

It is recommended that applicants having a skin test reaction of 10mm or more but a normal chest radiograph be referred to the local health department to be considered for preventive therapy. However, this is not a requirement and is left to the discretion of the civil surgeon.

Efforts are underway to investigate ways to strengthen the training and referral system for the civil surgeons.

—Reported by Nancy Binkin
Division of TB Elimination
Dick Moyer
Division of Quarantine

NEWS BRIEFS

A program entitled “The People’s Plague: Tuberculosis in America” will be broadcast on October 2, 1995, from 9:00 to 11:00 pm EST on your local PBS station. This video, produced by Emmy Award winners Diane Garey and Lawrence Hott, chronicles a history that has shaped much of our modern public health policy. The 2-hour documentary characterizes every aspect of today’s health care debate, from delivery of

service to cost containment, from disease prevention to social control. Told through the personal stories of dozens of TB survivors, and from the point of view of health care workers, researchers, and TB victims of today, this is a “must see” for everyone who cares about our history and our future health. The People’s Plague has received major funding from the Corporation for Public Broadcasting, the National Endowment for the Humanities, and The Arthur Vining Davis Foundations, and is presented in cooperation with the American Lung Association.

The three model TB centers—the Francis J. Curry National Tuberculosis Center in San Francisco, Harlem Hospital Center in New York City, and the New Jersey Medical School National Tuberculosis Center in Newark—plan to conduct three collaborative training sessions this year. One has been completed: “The Scientific Basis of TB Control” was held on May 20 at the ALA/ATS meeting in Seattle. Tapes of the presentations were telecast in three parts beginning in late June; each telecast featured a live follow-up session for call-in questions and answers. On October 31, the model centers will conduct a 3-hour program called “The Resurgence of Tuberculosis: A Decision Maker’s Guide to Turning it Around” at the meeting of the American Public Health Association in San Diego. Its purpose will be to bring TB to the attention of the people who attend the meeting. Two days later, model center staff will conduct a 90-minute symposium called “Managing the New Tuberculosis Epidemic” at the American College of Chest Physicians in New York City.

A hotline for questions on tuberculosis has been opened by the A.G. Holley State Hospital in Lantana, Florida, which is the last of the original TB sanitoriums and the only free-standing American hospital dedicated exclusively to TB. A call to 1-800-4-TB-INFO from anywhere in the United States at any hour will be returned with information on any aspect of tuberculosis. Questions are welcome from physicians, patients, nurses, pharmacists, infection control specialists, attorneys, and any others. This service is funded by a grant from CDC.

PERSONNEL NOTES

Jose Becerra, M.D., M.P.H., joined DTBE on July 31 as the Chief of the Computer and Statistical Services Activity. Before coming to DTBE he was assigned to the Division of Reproductive Health, Research and Statistics Branch, NCCDPHP. Jose has been with CDC for 10 years; he has spent the past 4 years in Puerto Rico where he served as a liaison with the Puerto Rico Department of Health and the University of Puerto Rico School of Public Health. Fred Ingram, who previously headed the Computer and Statistical Services Activity, will continue to be an integral member of that activity.

Cindy Driver, R.N., M.P.H., has left CDC and has accepted a position with the New York City Department of Health (NYCDOH). Cindy was with DTBE for 3 years where she was an Epidemic Intelligence service (EIS) officer; she served as a Nurse Epidemiologist with the Surveillance and Epidemiologic Investigations Branch (SEIB), DTBE. She worked on outbreak investigations and epidemiologic investigations of TB in children. Prior to this Cindy worked with the maternal and infant care project in NYCDOH.

Mark Fussell has been selected for the public health advisor position in the Florida TB program. Mark has been on assignment to the California TB program since April 1993. He transferred from Berkeley to Tallahassee on July 23, 1995.

Larry Geiter has left CDC to join the staff of the International Union Against Tuberculosis and Lung Disease (IUALTD) in Washington, D.C. For the past 4 years Larry has been the Chief of the Clinical Research Branch in DTBE. Larry came to CDC in 1984 as a Clinical Studies Analyst in the Clinical Studies Section of DTBE. Before coming to CDC Larry worked for the state of Arizona in the Division of Disease Control Services. He also spent 2 years as a TB control worker with the Peace Corps in Korea. Interestingly, he received his Peace Corps training in TB epidemiology and the principles of TB control from a scientist who preceded him in joining DTBE, Dr. George Cauthen.

Bob Good, Ph.D., has retired from CDC after 19 years of service. Bob joined CDC in 1976 as the chief of the Mycobacteriology Branch in the Bureau of Laboratories, which later became the Respiratory Diseases Branch in the Division of Bacterial and Mycotic Diseases. As the supervisor of mycobacteriology lab projects, Bob served as a valuable resource for DTBE and other CDC staff regarding laboratory issues and questions. He was one of the coinvestigators in an important survey of primary drug resistance conducted from 1975 to 1986; in this survey, Dr. Good's laboratory performed a large volume of very exacting lab work, testing approximately 16,000 *M. tuberculosis* specimens for drug resistance. The

mycobacteriology lab is also a well-known reference laboratory to which other laboratories send unusual specimens for analysis. During Dr. Good's tenure, several new TB lab techniques were implemented in the TB laboratory: the radiometric technique; the gene probe technique; phage typing; high performance liquid chromatography (HPLC) typing; the restriction fragment length polymorphism (RFLP) technique; and the polymerase chain reaction (PCR) technique. His ability to manage with diminishing resources and willingness to share his expertise were respected and appreciated.

Veronica Greene, D.D.S., M.P.H., joined the Clinical Research Branch in July 1995 as a medical epidemiologist. Previously, she was an EIS officer from 1993 to 1995 in the Special Projects Section, Surveillance Branch, Division of HIV/AIDS. She will primarily work on the rifapentine clinical trial, various laboratory-related issues, and preventive therapy recommendations for persons exposed to MDR TB.

Sherry Hussain was selected for the position of branch secretary in the Clinical Research Branch, DTBE. Previously, she was a secretary in the National Center for Chronic Disease Prevention and Health Promotion for 2 years. Sherry is not new to the division; from 1985 to 1988 she was the branch secretary in the Research and Development Branch, the forerunner of CRB, DTBE.

Jeannette Houston has joined DTBE as the Office Automation Assistant of the Program Support Section, Program Services Branch. Jeannette comes to Atlanta from Anniston, Alabama, where she was employed by the Anniston Army Depot. Jeannete has had over 12 years of experience with the Federal government in a variety of support positions.

Linda Leary of the Program Support Section, Program Services Branch, DTBE, has been accepted into the Women's Executive Leadership Program. This is a program that provides supervisory and managerial training and developmental opportunities for employees, thereby preparing them for future leadership positions. She will stay in her current position and continue with her present responsibilities during her participation in the program. Linda is responsible for collecting, maintaining, and interpreting program management data from state and city TB programs throughout the nation. In addition, she will continue to coordinate all HIV-Related TB Prevention (HRTP) activities.

Mary Anne Lyle has retired after 42 years of service with CDC. Mary Anne was a Clinical Studies Analyst in the Clinical Research Branch, DTBE. She joined CDC in 1952 in the Epidemiology Branch as a Clerk/Typist; her supervisor was Dr. Alexander Langmuir. She was in the polio unit at the time of Dr. Jonas Salk's discovery of the polio vaccine. In 1966 she went to work in the smallpox program and

was involved in the smallpox eradication program. In 1971 she joined the nutrition program, where she trained and supervised public health advisors who were assigned to complete the Ten-State Nutrition Report. In 1973 she joined DTBE as a Statistical Assistant. During her 22 years in DTBE she had a major role in several of the clinical trials for TB drugs and regimens, including the current TB Consortium, which is testing rifapentine.

Diana Mazzella has been selected for the position of branch secretary in the Program Services Branch, DTBE. Before coming to DTBE Diana was a secretary in the Division of HIV/AIDS, NCID.

Michelle McMacken has resigned from CDC in order to pursue pre-med studies at Gaucher College in Baltimore, Maryland. Michelle was a Writer/Editor with DTBE for 3 years. Prior to that, she held several editorial positions in the Washington, D.C., area. Some of Michelle's accomplishments included writing speeches, publishing TB Notes, editing articles for scientific journals, developing the DTBE Voice Information System, and developing the training modules used in the Satellite Primer on Tuberculosis which was broadcast this spring.

Marisa Moore, M.D., M.P.H., joined SEIB on July 25 as an EIS officer. Prior to joining DTBE she was a preventive medicine resident with the Arizona Department of Health. Marisa is a board certified internist.

Valecia (CheeChee) Parker has resigned from CDC and accepted a promotion with the National Institute of Mental Health as a secretary. She came to work for CDC as the branch secretary of the Program Services Branch in April 1994. Prior to that she was with the Division of STD/HIVP.

Judy Rudnick, M.D., has resigned from CDC to join a private medical practice in Stone Mountain, Georgia. Judy had been a medical epidemiologist in the Clinical Research Branch since July 1993. Prior to that, Judy was an EIS officer with the Hospital Infections Program, NCID.

Eileen Schneider, M.D., joined SEIB on August 1 as an epidemiologist in the Surveillance Section. Before coming to DTBE she was with the Epidemiology Program Office assigned to the San Diego County health services office, where she completed her EIS assignment. While there she completed a variety of epidemiologic assignments.

Joann Schulte, D.O., joined SEIB on August 4 as an epidemiologist in the Epidemiology Section. She was with the Texas Department of Health before coming to DTBE; prior to that, Joann was an EIS officer with the Division of STD/HIV Prevention.

Paul Schwartz has retired from CDC after 33 years with the U.S. Government, 31 of which were with CDC. Paul joined CDC in 1963 as a

public health advisor in the STD program (formerly the VD control program) in Los Angeles. He had subsequent VD program assignments in Kansas City, Kansas, and Jersey City, New Jersey, before joining the TB program in 1968. His assignments with the TB program took him to the City of New Orleans and to the state health departments of Louisiana, Oklahoma, Ohio, and Texas. In 1989 Paul joined the staff of DTBE in Atlanta as a program consultant. He has served as the consultant for Regions V and X and the territories of Region XI.

Jordan Tappero, M.D., has joined the International Activity of DTBE. Jordan is an internist and dermatologist who was trained at the University of Arizona and the University of California, San Francisco. He was an EIS officer and subsequently a preventive medicine resident before joining DTBE as a staff epidemiologist. He will be working on a variety of international projects on methods for improving TB diagnosis in developing countries. He will also be examining community transmission of TB in settings of high HIV prevalence.

Andrew Vernon, M.D., M.H.S., joined the Clinical Research Branch in May. His primary responsibility will be serving as a project officer for the branch's ongoing clinical trial of rifapentine and INH vs. rifampin and INH. For the previous 18 months he had been a Field Epidemiologist in the Georgia TB Epidemiology Department of the Georgia Department of Human Resources. Dr. Vernon has been with CDC since 1978. He has served in two state health departments (Oklahoma and Georgia) and in one overseas post (Kinshasa, Zaire). In addition, he spent 4 years in Baltimore, completing an infectious disease fellowship, earning a master's degree in health science, and coordinating HIV-related clinical trials.

Charles Wells, M.D., is an EIS officer who is also joining DTBE in the International Activity. He is an internist who was trained at Emory University. He will be working on issues related to TB in foreign-born persons in the United States, such as finding ways to improve the overseas screening of immigrants and refugees, and describing TB among foreign-born Hispanics in counties along the U.S.-Mexican border in conjunction with TB programs in California, New Mexico, Arizona, and Texas.

NEW PUBLICATIONS

Journal Articles

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TRAINING AND EDUCATIONAL MATERIALS

Infection Control Questions and Answers [videotape]. Santa Monica, Calif: Quality Line Enterprises; April 1995. Filmed in a hospital and intended for health care workers, this new 18-minute videotape answers infection control questions pertaining to the specific jobs and departments of various employees. Topics include TB isolation and respiratory protection, modes of transmission, and identification and confidentiality. It includes a variety of other infection control issues, including bloodborne and contact pathogens. The cost is $199 per videotape plus $8 for shipping and handling (in California, add 8.25% sales tax). The videotape may be previewed for 7 working days for an $8 shipping fee. To order copies, call or write

Quality Line Enterprises
309 Santa Monica Blvd., Suite 202
Santa Monica, CA 90401
(800) 356-0986

CALENDAR OF EVENTS

October 16-20, 1995; February 12-16, 1996;
April 22-26, 1996
Postgraduate Course on Clinical Management and Control of Tuberculosis
Denver, Colorado
Catheryne J. Queen
National Jewish Center for Immunology and Respiratory Medicine
(303)398-1700

Association of Asian Pacific Community Health Organizations (AAPCHO)

Targeting TB in Asian Pacific Islander Communities

Recommended TB Health Education Materials in Asian/Pacific Islander Languages

October 29-November 2, 1995
American Public Health Association Meeting
San Diego, California
(202)789-5646

February 5-8, 1996
Advanced Mycobacteriology:
A Hands-On Four-Day Course for Laboratorians
Boston, Massachusetts
Ann Day, NE Office
National Laboratory Training Network
(617)983-6284

AAPCHO will provide *one* copy of any title on this list; to order, contact Mr. Jeff Caballero, (510)272-9536. For information on ordering *multiple* copies, contact the following vendors directly.

TITLE	Available in English as well as the following LANGUAGE(S)	SOURCE
General Information		
1. *The Connection Between TB and HIV*	Korean Vietnamese	Developed by CDC; translated copy available from Asian Health Services (510)465-3374
2. *Stop TB!*	Chinese Ilocano Korean Tagalog Vietnamese	Developed by CDC; translated copy available from AAPCHO (510)272-9536

Association of Asian Pacific Community Health Organizations (AAPCHO)

Targeting TB in Asian Pacific Islander Communities

Recommended TB Health Education Materials in Asian/Pacific Islander Languages

3. *TB: Get the Facts!*	Chinese Korean Tagalog Vietnamese	Developed by CDC; translated copy available from AAPCHO (510)272-9536
4. *Let's Knock Out The TB Germ*	Ilocano	Hawaii ALA/Hawaii State Dept. of Health (808)537-5966
5. *TB: It Can Happen to You*	Korean Chinese	American Lung Assoc., Los Angeles County (213)935-5864

TITLE	LANGUAGE	SOURCE
6. *What You Should Know About TB*	Chinese Ilocano Korean Tagalog Vietnamese	AAPCHO (510)272-9536

Note: The above publications, *Stop TB!* and *What You Should Know About TB*, will be available after October 1995.

Treatment:

7. *What is TB, Class III & V*	Chinese Korean Tagalog Vietnamese	California TB Controllers Assn. and California Dept. of Health Services (714)834-8243

Association of Asian Pacific Community Health Organizations (AAPCHO)

Targeting TB in Asian Pacific Islander Communities

Recommended TB Health Education Materials in Asian/Pacific Islander Languages

The Creative Use of Incentives in TB Control and Prevention

Susan J. Eastman and Kathryn Judd

Introduction

The Robert Wood Johnson Foundation (RWJ) established the program, "Old Disease, New Challenge: Tuberculosis in the 1990s," to support efforts to address the resurgence of TB. In response to a solicitation by the Foundation for innovative projects, 143 concept papers were received in 1993. Ultimately five projects were selected for funding (in California, Florida, Georgia, Maryland, and New York) at a financial commitment of $5.5 million. Although not all 143 proposed projects could receive RWJ funding, the reviewers were impressed with the variety of the creative initiatives described. In collaboration with the project investigators, the national program office consolidated selected suggestions on the use of incentives in TB control and prevention for general distribution and possible replication.

In a CDC publication, the principle of improving patient adherence to TB medications is best summarized by the exhortation of a public health nurse: "What we do is whatever it takes!"[1] In many TB control programs, "whatever it takes" involves the use of incentives. In fact, the use of incentives, i.e., small rewards, has become standard operating procedure.[2, 3] At the same time, little is known about their relative effectiveness.[4] The vignettes presented here offer innovative interventions to be tried and evaluated. They represent an open-minded playing field where the players can do whatever it takes. The following look at the use of housing, conditional, humane, methadone, and monetary incentives.

Housing incentives

A. Background

TB is often entrenched in populations with unstable housing, where infection rates are as high as one third of the homeless in San Francisco and range from 18% to 51% elsewhere.[5, 6] The instability makes follow-up and directly observed therapy (DOT) efforts particularly difficult. Housing status is an important indicator or predictor of nonadherence.[7] Unstable housing can also result in inadequate or incomplete TB screening. Some programs have introduced innovative strategies to provide temporary housing for the duration of therapy.[8] A number of proposals incorporated housing as a positive incentive, ranging in their degree of involvement from referral agent to sponsor.

B. Description and Location

New York/Bellevue Hospital Center; Texas/Dallas Urban League; Texas/Harris County Sheriff's Department

In Texas, the Dallas Urban League (in collaboration with the Dallas County Health Department, University of Texas Health Science Center, Department of Health and Human Services, and Correctional Authority) hopes to empower correctional inmates and parolees to access social and

health services. The project provides shelters and alternative living arrangements as required, as well as a special rental and utility subsidy on a 6-month basis for clients with a history of noncompliance.

Another project in Texas also addresses the inmate/parolee population. This Houston-based initiative is a collaboration between the University of Texas Medical School and Harris County. The project will follow the inmates while in correctional facilities and after release into the community. Those individuals leaving the jail or juvenile center who do not have stable home addresses will be identified prior to their release. The Coalition for the Homeless of Houston and Harris County will facilitate the arrangement of subcontracts with local homeless shelters to provide room and board as an incentive to complete 6 months of DOT. This is in addition to persons released to residential drug treatment centers, HIV clinics, or halfway houses.

The most systematic user of housing as an incentive is a coalition lead by the Bellevue Hospital Center in New York. This project considers access to social services as both an incentive and a necessity for their "Shared Responsibility Model." The project hopes to shift the locus for posthospital care back to the community by supporting and collaborating with community based organizations (CBOs). An integral function is expediting placement in housing and other CBO programs to encourage completion of treatment. The model will combine state-of-the-art medical capacity at Bellevue with CBO-based programs and services. These include methadone maintenance; supportive housing; meals; and other psychiatric, vocational, rehabilitational, and substance abuse services.

Each CBO will jointly recruit a Community Liaison Worker (CLW) who will assist in screening and expediting referrals. For example, a patient domiciled by Housing Works might also be given follow-up for drug treatment at The Educational Alliance. For a homeless patient, the opportunity to be prioritized for housing units made available by Housing Works may offer a strong incentive to complete the course of treatment. Housing is made available through various kinds of programs, policies, and legislation: New York requires all HIV-positive patients to have housing; New York State's Community Pilot Placement Program (CPPP) provides apartments for patients who are on DOT or DOPT and are HIV positive; another service provides housing to those under a "psychiatric diagnosis"; a large shelter adjacent to Bellevue Hospital is available to homeless persons; and finally, social workers try to find housing for women with children.

Additional health and social services made available through the local CBOs are the methadone and drug-free residential program (Lower East Side Service Center), medical treatment (Community Health Project), and other residential programs (The Educational Alliance and BRC Human Services Corporation). The CLW workers will meet regularly to share information about the clients and facilities.

C. Issues to Consider

Three main issues to consider regarding the use of housing as an incentive are contagion, cost, and coordination. The highly infectious patient will be isolated to the extent required by the respective health department. This might be accomplished through short-term hospitalization or

by using single room occupancy (SRO) facilities or special quarters set up in shelters. Each CBO is taught to implement infection control procedures internally. They must rule out TB on-site. The staff plant PPDs and have a structured questionnaire to help identify symptoms. Clients who come with obvious symptoms are referred to the clinic or the emergency room, depending on the symptoms displayed and whether or not they are PPD positive. If TB disease is suspected, patients will be admitted to the hospital.

In terms of cost, the budget for sheltering the homeless can be placed within an existing mandate (i.e., social services). However, the need for special facilities combined with an active case-seeking initiative can burden any current funding. The issue of who will pay remains critical. In addition, to take advantage of State-subsidized services, patients must contribute a percentage of their entitlements. Some refuse to do this and would rather try to make it on their own. Part of the reason might be that the patient does not want to leave his or her neighborhood or Manhattan.

Finally, the coordination of the patient from hospitalization (or clinic) through the maze of bureaucracies to ensure disability and social security benefits logically rests with a social worker (rather than with the nurse or physician). Staff will need to be identified. The Bellevue project in New York has set up a mechanism for coordinating the patient flow and for collaborating with existing CBOs.

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Conditional incentives

A. Background

TB affects communities with limited access to care, limited knowledge of the disease, and life styles which preclude the pursuit of either care or knowledge, control strategies evolved to include conditional incentives for nonadherence to medication regimens. Two such strategies included in program proposals were from Raleigh, North Carolina, and New Haven, Connecticut. There is background support for the use of conditional incentives in both contexts suggested in the proposals: institutional confinement and conditions for welfare.

Iseman et al. reported in 1993 that a DOT program in Denver calls for each missed dose to be followed first by a phone call, and then by a visit from a deputized community worker with authority to replace DOT with confinement in an institution. Issuance of an order requiring either physical confinement or legally mandated observed therapy allows the judicial system to respond promptly when a patient fails to appear for treatment.[9] In fact, San Joaquin County in California has a proactive program of "policing" the TB beat. The District Attorney's Office, in collaboration with the County's TB Control Office, routinely releases no-bail arrest warrants for runaway TB patients. The County has an active DOT program with positive incentives. It only uses jail as a last resort. These potential inmates are often those who are utterly disenfranchised and desperately need support. The County considers they are literally saving their lives in having them so quarantined.[10,11] In terms of welfare, New York City's Human Resources Administration has a two-part medical examination mandated for any potential welfare client. If clients do not attend both parts of the examination, they cannot receive public assistance. This permits use of the Mantoux screening skin test. The return rate for the second part is reported at 93%.[12]

B. Description and Location
Raleigh, North Carolina, and New Haven, Connecticut

The intention of the Raleigh, North Carolina, project is to reduce TB incidence among young adults in the prison population. The project was developed in collaboration between the Communicable Disease Control Section of the North Carolina Department of Environment, Health, and Natural Resources, and the Office of Health Services of the Department of Correction. Discussions were preliminary, and funds were not secured. In 1992, 17% of prisoners had positive PPDs. The project proposed creating a computerized TB information system and evaluating DOT approaches using positive and conditional incentives. The positive incentives included assistance in obtaining health and other services to generate patient trust. However, what is unique about the project is the reported willingness to make adherence to therapy a condition of parole. The Director of the North Carolina Parole Commission was willing to discuss this condition for appropriate individuals. The project also hoped to work with the Parole Commission to develop protocols whereby the parole offices could be involved in the administration of DOT and DOPT.

The New Haven, Connecticut, citywide project proposes a collaboration between Yale University School of Medicine and New Haven's Health and Welfare Departments. It targets TB control among high-risk populations. The purpose is to improve TB screening and follow-up within the

societal context in which the epidemic has arisen. One component is a follow-up to a successful pilot project with the New Haven Welfare Department. The intervention will take advantage of a standard two-visit intake procedure by which welfare applicants must present for an initial screening and then return 2 days later to receive their first welfare check. This will allow for the integration of a TB screening skin test.

C. Issues to Consider

The above examples demonstrate collaboration between public institutions working with at-risk populations. One issue involves the potential for problems in confidentiality. The wider the net for intervention, the larger the number of persons with access to medical histories. The second issue involves the efficiency of targeting the whole welfare population. Each community will need to look at the TB prevalence within its target groups to determine the cost-effectiveness of screening a major group. Screening involves time, money, and staff (i.e., in training and providing back-up x-rays). At the same time, these programs take the threat of the TB epidemic seriously and recommend the use of any legally mandated public health regulations when necessary to control the spread of infection. In fact, one participant did not consider use of the jail system as a "conditional" incentive since it was saving the lives of some very disenfranchised citizens.

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Humane incentives

A. Background

Since TB often occurs in populations with limited social support and nurturing, some projects are emphasizing the long-standing mandate for treating the client with warmth, dignity, and love. Background references support the critical role played by the relationship between provider and

patient.[4,13,14] It is expressed in its position in health belief models[15,16], decision models[17], and patient education models.[18] Two strategies highlighting a particularly humane approach to TB control were included in program proposals from the Harlem Hospital in New York and the School of Nursing at the University of Michigan.

B. Description and Location
New York/Harlem Hospital and Michigan/University of Michigan

The Harlem Hospital project proposes a model which is a "safe refuge," where the clients will receive love, respect, attention, and affection, in addition to the expanded services they need. The project promotes a "family model," which will also use incentives at strategic points in treatment. A pilot project effectively demonstrated the importance of a welcoming environment, providing continuity of care in the use of a single medical provider for each patient, in remembering birthdays, and in individualizing care plans. The patients will be asked to identify buddies who will be familiar with each other's appointments. Patients might become peer counselors. Any incentives are used to promote empowerment, decision-making, and skill building. The goal is that each individual patient will decide the need for and choice of incentives.

The patient will be invited to join the DOT family during his or her hospitalization. At this stage, specific incentives such as self care items (comb, clippers, shampoo), in-room television and telephone services, nutritious snacks, and referrals to a social worker for postdischarge needs will be made available. Once committed, there will be recognition of "treatment landmarks" such as the first day of appearance at the DOT site, completion of the first 2 weeks of treatment, completion of half the treatment course, and full completion of the treatment course. Individualized incentives are to be taken from a list ranging from outpatient care packages, subway tokens, meal coupons, and clothing store certificates. Full completion will also be recognized in an awards ceremony and through the gift of a small item of electronic equipment. The project believes that compliance is enhanced when the patient feels important and respected, and is the focus of the provider-patient interaction.

The aim of the University of Michigan project is to demonstrate that health care providers can influence adherence by building relationship skills. That is, nurses who interact with TB patients can have a direct influence on improving the patients' adherence to the treatment regimen by providing culturally sensitive, gender- and class-specific verbal cues that prompt the patients to identify and discuss any problems they are having. This reinforcement (through the systematic provision of cues) can demonstrate to the patients that the nurse represents a sensitive and supportive environment where it is safe for the patients to reveal problems with adherence and appointment keeping.

The patient behaviors to be targeted and encouraged include asking questions, registering concerns and complaints, reporting symptoms and medication side effects, identifying problems with medication taking and appointment keeping, and expressing a need for the clinic staff to help them better manage their TB disease or infection. The ultimate intent of this behavioral training intervention is to increase collaborative problem solving, individualize the prescribed

regimen, and help health care providers approach patients in a way that is sensitive to culture, gender, and class.

C. Issues to Consider

Both of the above examples focus on the need for a dynamic interaction between the patient and provider, which is mutually reinforced through cues, concern, incentives, and attention. The Harlem Hospital explicitly encourages the return to a personal, loving environment to sustain patients through their illness and full recuperation. This "etiquette of caring" might be construed as overly personal. However, both projects involve empowering the client through collaborative decision making and skills building and by identifying tools to build a relationship. The subsequent interactions reinforce both the individual and the partnership.

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Methadone incentives

A. Background

TB programs have also introduced innovative strategies to reach out to populations with addictive life styles. In San Francisco, two proposed programs recommend the use of methadone maintenance as an incentive to maintain client participation throughout the duration of treatment. The integration of health care and drug treatment is supported elsewhere. For example, in Connecticut, a primary care unit was established for those enrolled in drug treatment to both provide service and facilitate compliance.[19] Providing incentives to support participation in a treatment program has also been indicated.[20] In the following cases, one project hopes to look at the possible advantage of admission to a methadone maintenance program in ensuring compliance; the latter takes advantage of the treatment facility to identify undiagnosed TB

infection and improve compliance.

B. Description and Location
San Francisco/Bay Area Addiction Research and Treatment (BAART) and San Francisco/ General Hospital

Based at San Francisco General Hospital, the first project proposes to demonstrate the effectiveness of methadone maintenance treatment as a setting for TB chemoprophylaxis. PPD testing is part of the initial work-up offered to patients entering the detoxification program. As the standard protocol, the PPD-positive patient is referred to the public health department TB clinic for follow-up. However, results from a limited review of medical records indicate that of those patients referred from the detoxification treatment and started on INH, none completed the entire 6 months of chemoprophylaxis. In the proposed study, out-of-treatment PPD-positive injection drug users (IDUs) will be admitted to the 21-day methadone detoxification, then randomly assigned to either the program group (as part of "6-months-plus-1" methadone maintenance treatment combined with daily on-site administration of isoniazid) or standard care (no further methadone treatment and referral to the public health TB clinic). The primary outcome will be the proportion of subjects who complete a 6-month course of TB chemoprophylaxis. A revised version of this proposal has recently been funded by the National Institute on Drug Abuse (NIDA).

The other proposal is from a community based organization, Bay Area Addiction Research and Treatment, which is a substance abuse treatment facility with 10 clinics in four counties. The primary goal of the TB control component is to find previously undiscovered cases of TB among IDUs, enroll them in treatment, and ensure adherence to treatment. The project proposes offering free 120-day methadone maintenance to PPD-positive detoxification patients with a $50 incentive for proof of a chest x-ray, and long-term methadone maintenance to patients who have active TB or who are HIV positive with a $15 incentive at the end of each month of DOT. The proposal is not yet funded.

C. Issues to Consider

These proposals are unique in their effort to take advantage of the needs of the patients in providing TB prophylaxis or treatment in a drug treatment setting. Another suggested intervention for evaluation would be to use entry into the methadone program itself as a direct incentive, as well as the above screening procedures of clients already enrolled. The population is at high risk to themselves and others. Combining the therapies maximizes the opportunity.

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Monetary incentives

A. Background

One of the few published reports looking at monetary incentives found that this "special intervention" was effective in improving adherence to treatment and prophylaxis.[18] However, the intervention included both health education counseling and monetary incentives, without distinguishing the independent impact of either. The incentives included $5 for infected TB patients and $10 for active TB patients, in either cash or cash-equivalent goods. The study also suggested that a nonmonetary incentive may appeal to a number of individuals, but its value may have to be considerably increased and tailored to individual needs. In a state-of-the-art review, another author agrees that incentives such as money are recommended to improve adherence; however, little systematic research has been carried out to assess effects.[4]

B. Description and Location
University of California/San Francisco School of Medicine and San Francisco General Hospital

San Francisco has undertaken the most systematic studies examining the use of monetary awards in recent field research. Two ongoing field projects are worth detailing. One UCSF study in collaboration with the San Francisco General Hospital highlights the potential use of recruiting "peer health advisors" to improve adherence. Funded by the Henry J. Kaiser Family Foundation, this community-based controlled trial addresses hard-to-reach populations involving the homeless, unstably housed, or domiciled poor who are infected with TB and/or HIV. The patients are randomized into one of three interventions: the "peer health advisor" (PHA), with the PHA assisting in clinic visit and DOT; the "monetary incentive," whereby the subjects are provided $5 in cash for follow-up at the clinic and for each DOT dose twice weekly; and "usual care" whereby the subject is informed about TB and a clinic appointment is given with a bus token and map. Preliminary results indicate that monetary incentives alone might be the most effective and efficient approach.

The second project is out of the Urban Health Study with the UCSF School of Medicine. The "Four Models of Delivery of INH Chemoprophylaxis to Injection Drug Users" is a controlled randomized trial comparing adherence between types and costs of various DOT interventions.

The model presumed to have the highest adherence rate is the incentive-based DOT, which involves twice-weekly payment for participation. Their earlier research found that increasing stipends from $5 to $10 made a dramatic difference in patients returning for results of HIV testing; in going from $10 to $15, the number of respondents recruited in the field site doubled. The current study compares four interventions: standard care (i.e., self-administered therapy); DOT in street settings (i.e., meet with patient twice weekly); indirectly observed therapy in street settings (i.e., provide patient with a month's supply of medication, work out suggested dosing schedule, make arrangements to meet every 2 weeks); and incentive-based DOT (monetary incentive of $10 cash, twice weekly, to return to a neighborhood-based location for DOT).

C. Issues to Consider

Monetary incentives are successful in increasing adherence. In spite of that, there is no consensus on their use. Issues range from the practical to those of principle. Practical issues involve cost and administration; issues of principle involve civic duty and the ultimate use of the money.

The costs of monetary incentives for an entire TB case population can be significant. An urban project with 500 patients on prophylaxis could spend $145,000 with a $5 incentive. In addition, not completing therapy with the single-drug protocol can result in drug-resistance. In New York, costs for treating a drug-resistant TB case can be $200,000. However, whether it is expensive or cost-efficient, the intervention still must be paid for. The ALA is often cited as a sponsor.

A second practical issue is administration. The handling of petty cash involves issues of accountability and control. The paperwork itself can be significant, with receipts, signatures and counter-signatures required. The amount of bureaucracy will depend on the source of funding. A staff person will need to take responsibility for obtaining and disbursing the funds.

Issues of principle involve value judgments on both the use of money to motivate the patient, as well as speculation on the ultimate use of the money. Some consider taking medication for an infectious disease to be a civic duty; that as a citizen, one has a responsibility to the community just by being a member. This assumes a homogeneity which often doesn't exist in the urban communities. Similarly, what the patient does with the incentive (i.e., buy food, drugs, toys) is essentially a private concern, and is beyond the scope of the TB project. Both judgments have implications larger than any public health disease involving the wholeness of the community itself.

The use of monetary incentives works to increase adherence. The systematic monitoring and dissemination of the results can lead to a better understanding of the range of program possibilities available.

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